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(54) **PATIENT FLUID LINE ACCESS VALVE
ANTIMICROBIAL CAP/CLEANER**

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patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

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CPC **A61M 39/162** (2013.01); **A61M 39/02**
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(Continued)

(58) **Field of Classification Search**
CPC ... A61M 39/16; A61M 39/20; A61M 39/162;
A61M 39/165

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,961,682 A 11/1960 Wurmbock et al.
3,047,139 A 7/1962 Jacoff

(Continued)

FOREIGN PATENT DOCUMENTS

EP 1 649 890 A1 4/2006
EP 2606930 A1 6/2013

(Continued)

OTHER PUBLICATIONS

“Corrected Petition for Inter Partes Review Under 35 U.S.C. §§
311-319 and 37 C.F.R. § 42,100 et seq.,” USPTO, Patent Trial and
Appeal Board, *Excelsior Medical Corporation v. Becton, Dickinson
and Company*, Case IPR2014-00880, U.S. Pat. No. 8,740,864, pp.
1-48, Jun. 23, 2014.

(Continued)

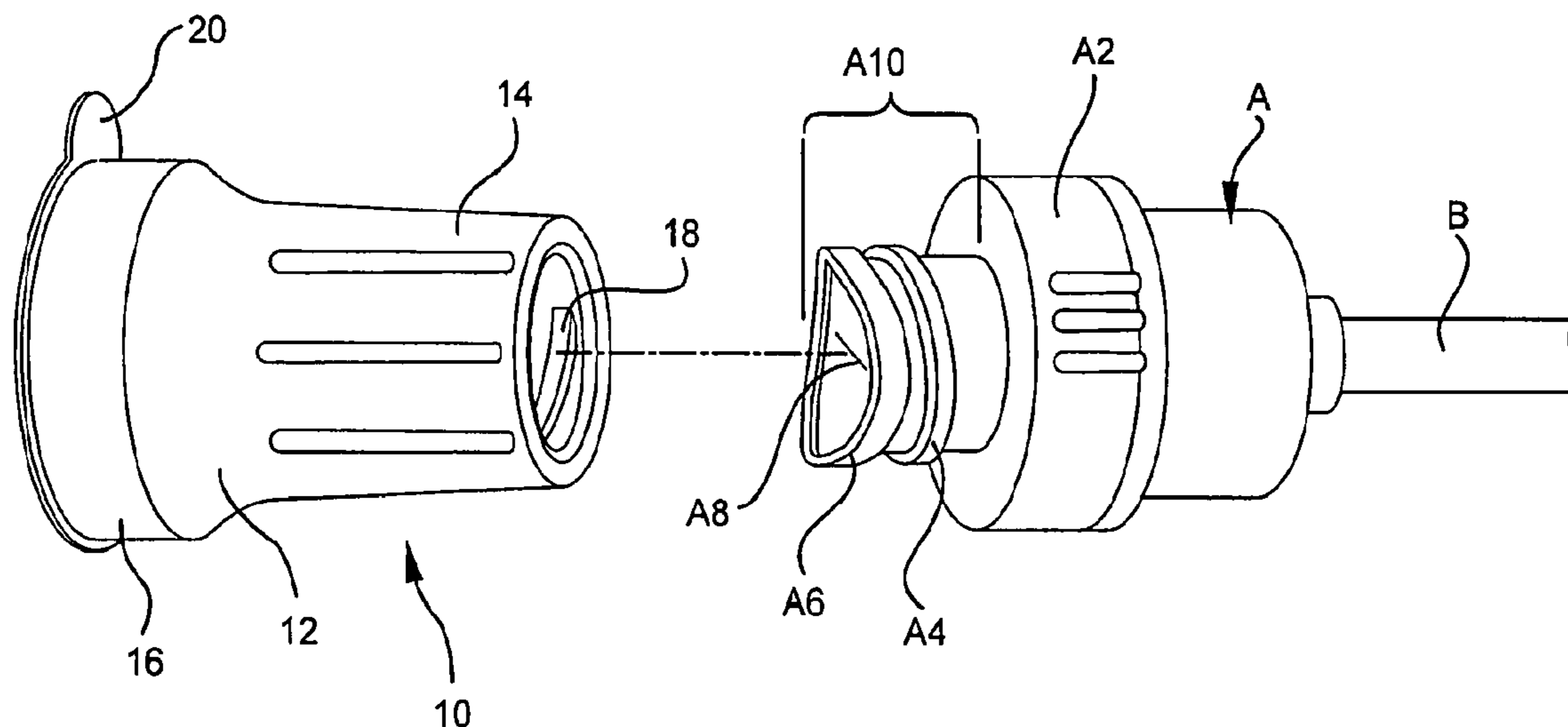
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(57) **ABSTRACT**

Cap and cleaning devices antiseptically maintain patient
fluid line access valves to minimize the risk of infection via
catheters. The devices have a cap that may contain a dry pad
impregnated with an antimicrobial agent. The cap covers the
access portion of the access valve when not in use. The
devices have a hood that contains a wet pad impregnated
with a cleaning solution and, optionally, an antimicrobial
agent. The wet pad cleans the access portion of the access
valve prior to and optionally, after the access valve is
utilized to access the patient fluid line.

14 Claims, 7 Drawing Sheets



Related U.S. Application Data					
No. 14/159,959, filed on Jan. 21, 2014, now Pat. No. 9,283,367, which is a continuation of application No. 11/281,711, filed on Nov. 17, 2005, now Pat. No. 8,740,864.		6,074,366	A	6/2000	Rogers et al.
		6,089,541	A *	7/2000	Weinheimer A61M 39/26 251/149.1
		6,116,468	A	9/2000	Nilson
		6,117,114	A *	9/2000	Paradis A61M 39/045 604/246
		6,146,360	A	11/2000	Rogers et al.
		6,196,998	B1	3/2001	Jansen et al.
		6,227,391	B1	5/2001	King
		6,337,357	B1	1/2002	Fukunishi et al.
		6,413,539	B1	7/2002	Shalaby
		6,416,496	B1	7/2002	Rogers et al.
		6,482,188	B1	11/2002	Rogers et al.
		6,488,942	B1	12/2002	Ingemann
		6,523,686	B1	2/2003	Bae
		RE38,145	E	6/2003	Lynn
		6,664,893	B1	12/2003	Eveland et al.
		6,665,385	B2	12/2003	Rogers et al.
		6,708,363	B2 *	3/2004	Larsen A61L 2/26 15/104.92
(51)	Int. Cl. <i>A61M 39/20</i> (2006.01) <i>A61M 39/04</i> (2006.01) <i>A61M 39/10</i> (2006.01)				
(52)	U.S. Cl. CPC <i>A61M 39/20</i> (2013.01); <i>A61M 39/045</i> (2013.01); <i>A61M 2039/1033</i> (2013.01); <i>A61M 2039/1072</i> (2013.01); <i>Y10T 137/4259</i> (2015.04)				
(56)	References Cited U.S. PATENT DOCUMENTS				
	3,136,416 A	6/1964	Goldrosen		
	3,147,876 A	9/1964	Lepore		
	4,280,632 A	7/1981	Yuhara		
	4,282,891 A	8/1981	Duceppe		
	4,354,490 A	10/1982	Rogers		
	4,417,890 A	11/1983	Dennehey et al.		
	4,432,764 A	2/1984	Lopez		
	4,440,207 A *	4/1984	Genatempo A61L 31/16 150/154		
	4,444,310 A	4/1984	Odell		
	4,584,192 A	4/1986	Dell et al.		
	4,624,664 A	11/1986	Peluso et al.		
	4,626,664 A	12/1986	Grise		
	4,655,762 A	4/1987	Rogers		
	4,671,306 A	6/1987	Spector		
	4,716,032 A	12/1987	Westfall et al.		
	4,778,447 A *	10/1988	Velde A61M 39/10 604/29		
	4,915,934 A	4/1990	Tomlinson		
	4,925,668 A	5/1990	Khan et al.		
	4,989,733 A	2/1991	Patry		
	4,991,629 A	2/1991	Ernesto et al.		
	5,006,114 A	4/1991	Rogers et al.		
	5,023,082 A	6/1991	Friedman et al.		
	5,195,957 A	3/1993	Tollini		
	5,197,620 A	3/1993	Gregory		
	5,242,425 A *	9/1993	White A61M 39/20 604/256		
	5,334,388 A	8/1994	Hoang et al.		
	5,335,373 A	8/1994	Dangman et al.		
	5,512,199 A	4/1996	Khan et al.		
	5,547,662 A	8/1996	Khan et al.		
	5,554,106 A	9/1996	Layman-Sipllar et al.		
	5,554,135 A *	9/1996	Menyhay A61M 39/162 138/89		
	5,569,207 A	10/1996	Gisselberg et al.		
	5,616,338 A	4/1997	Fox, Jr. et al.		
	5,620,424 A	4/1997	Abramson		
	5,639,310 A	6/1997	Giampaolo, Jr.		
	5,641,464 A	6/1997	Brigs, III et al.		
	5,686,096 A	11/1997	Khan et al.		
	5,694,978 A *	12/1997	Heilmann A61M 39/20 138/103		
	5,702,017 A	12/1997	Goncalves		
	5,706,944 A	1/1998	Hoang et al.		
	5,722,537 A	3/1998	Sigler		
	5,743,884 A	4/1998	Hasson et al.		
	5,792,120 A	8/1998	Menyhay		
	5,817,344 A	10/1998	Hoang et al.		
	5,861,440 A	1/1999	Gohla et al.		
	D410,081 S	5/1999	Sweeney et al.		
	5,954,957 A	9/1999	Chin-Loy et al.		
	5,989,229 A	11/1999	Chiappetta		
	6,045,539 A	4/2000	Menyhay		
	6,051,609 A	4/2000	Yu et al.		
				6,846,846	B2 1/2005 Modak et al.
				6,861,060	B1 3/2005 Luriya et al.
				6,911,025	B2 6/2005 Miyahara
				6,957,107	B2 10/2005 Rogers et al.
				6,979,323	B2 12/2005 Rogers et al.
				6,994,315	B2 2/2006 Ryan et al.
				7,002,468	B2 2/2006 Eveland et al.
				7,130,396	B2 2/2006 Rogers et al.
				7,083,605	B2 8/2006 Miyahara
				7,198,611	B2 4/2007 Connell et al.
				7,198,800	B1 4/2007 Ko
				7,268,165	B2 9/2007 Greten et al.
				7,282,186	B2 10/2007 Lake, Jr. et al.
				7,452,349	B2 11/2008 Miyahara
				D607,325	S 1/2010 Rogers et al.
				7,682,561	B2 3/2010 Davis et al.
				7,704,002	B2 4/2010 Fisher et al.
				7,704,935	B1 4/2010 Davis et al.
				7,780,794	B2 8/2010 Rogers et al.
				7,828,186	B2 11/2010 Wales
				7,857,793	B2 12/2010 Raulerson et al.
				7,922,701	B2 4/2011 Buchman
				7,985,302	B2 7/2011 Rogers et al.
				7,993,309	B2 8/2011 Schweikert
				8,065,773	B2 11/2011 Vaillancourt et al.
				8,069,523	B2 12/2011 Vaillancourt et al.
				8,113,731	B2 2/2012 Cable et al.
				8,162,899	B2 4/2012 Tennican
				8,167,847	B2 5/2012 Anderson et al.
				8,172,825	B2 5/2012 Solomon et al.
				8,177,761	B2 5/2012 Howlett et al.
				8,197,749	B2 6/2012 Howlett et al.
				8,206,514	B2 6/2012 Rogers et al.
				8,231,587	B2 7/2012 Solomon et al.
				8,273,303	B2 9/2012 Ferlic et al.
				8,290,129	B2 10/2012 Rogers et al.
				8,328,767	B2 12/2012 Solomon et al.
				8,336,151	B2 12/2012 Kerr et al.
				8,336,152	B2 12/2012 Vaillancourt et al.
				8,343,112	B2 1/2013 Solomon et al.
				8,388,894	B2 3/2013 Colantonio et al.
				8,419,713	B1 4/2013 Solomon et al.
				8,491,546	B2 7/2013 Hoang et al.
				8,506,538	B2 8/2013 Chelak
				8,523,830	B2 9/2013 Solomon et al.
				8,523,831	B2 9/2013 Solomon et al.
				8,628,501	B2 1/2014 Hadden
				8,641,681	B2 2/2014 Solomon et al.
				8,647,308	B2 2/2014 Solomon et al.
				8,647,326	B2 2/2014 Solomon et al.
				8,671,496	B2 3/2014 Vaillancourt et al.
				8,696,820	B2 4/2014 Vaillancourt et al.
				8,721,627	B2 5/2014 Alpert
				8,740,864	B2 * 6/2014 Hoang A61M 39/02 604/267
				8,777,504	B2 7/2014 Shaw et al.
				8,789,713	B2 7/2014 Koller
				8,808,637	B2 8/2014 Ferlic
				8,828,327	B2 9/2014 Colantonio et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

8,832,894 B2 9/2014 Rogers et al.
 8,834,650 B2 9/2014 Rogers et al.
 8,845,593 B2 9/2014 Anderson et al.
 8,961,475 B2 2/2015 Solomon et al.
 8,968,268 B2 3/2015 Anderson et al.
 8,999,073 B2 4/2015 Rogers et al.
 9,101,750 B2 8/2015 Solomon et al.
 9,259,535 B2 2/2016 Anderson et al.
 9,283,367 B2* 3/2016 Hoang A61M 39/02
 2001/0016589 A1 8/2001 Modak et al.
 2002/0144705 A1 10/2002 Brattesani et al.
 2003/0040708 A1 2/2003 Rogers et al.
 2003/0072781 A1 4/2003 Pelerin
 2003/0109853 A1 6/2003 Harding et al.
 2003/0153865 A1 8/2003 Connell et al.
 2003/0162839 A1 8/2003 Symington et al.
 2004/0004019 A1* 1/2004 Busch A61B 17/3401
 206/571
 2004/0039349 A1 2/2004 Modak et al.
 2004/0073171 A1 4/2004 Rogers et al.
 2004/0258560 A1* 12/2004 Lake, Jr. A61L 2/18
 422/28
 2005/0124970 A1 6/2005 Kunin et al.
 2005/0147524 A1* 7/2005 Bousquet A61L 2/18
 422/28
 2005/0147525 A1 7/2005 Bousquet
 2005/0165351 A1 7/2005 Tamagni, Jr.
 2005/0222542 A1* 10/2005 Burkholz A61M 35/006
 604/289
 2006/0030827 A1 2/2006 Raulerson et al.
 2006/0165751 A1 7/2006 Chudzik et al.
 2006/0239954 A1 10/2006 Sancho
 2007/0112333 A1 5/2007 Hoang et al.
 2007/0202177 A1 8/2007 Hoang
 2007/0225660 A1 9/2007 Lynn
 2007/0282280 A1 12/2007 Tennican
 2008/0027399 A1 1/2008 Harding et al.
 2008/0033371 A1 2/2008 Updegraff et al.
 2008/0075761 A1 3/2008 Modak et al.
 2008/0086091 A1* 4/2008 Anderson A61M 5/31511
 604/192
 2008/0095680 A1 4/2008 Steffens et al.
 2008/0147047 A1* 6/2008 Davis A61M 39/165
 604/533
 2008/0177250 A1* 7/2008 Howlett A61M 39/165
 604/533
 2008/0182921 A1 7/2008 Suh et al.
 2008/0235888 A1* 10/2008 Vaillancourt A61L 2/235
 15/104.94
 2008/0283534 A1 11/2008 Paz
 2009/0008393 A1 1/2009 Howlett et al.
 2009/0028750 A1 1/2009 Ryan
 2009/0028756 A1 1/2009 Shahriari
 2009/0062766 A1 3/2009 Howlett et al.
 2009/0149819 A1* 6/2009 Chelak A61M 39/162
 604/246
 2009/0175759 A1 7/2009 Davis et al.
 2010/0000040 A1 1/2010 Shaw et al.
 2010/0047123 A1 2/2010 Solomon et al.
 2010/0049170 A1 2/2010 Solomon et al.
 2010/0050351 A1 3/2010 Colantonio et al.
 2010/0172794 A1 7/2010 Ferlic et al.
 2010/0204648 A1 8/2010 Stout et al.
 2010/0292673 A1 11/2010 Korogi et al.
 2010/0306938 A1 12/2010 Rogers et al.
 2011/0150958 A1 6/2011 Davis et al.
 2011/0232020 A1 9/2011 Rogers et al.
 2011/0265825 A1 11/2011 Rogers et al.
 2011/0290799 A1 12/2011 Anderson et al.
 2011/0314619 A1 12/2011 Schweikert

2012/0016318 A1 1/2012 Hoang et al.
 2012/0039765 A1 2/2012 Solomon et al.
 2012/0078203 A1 3/2012 Gaube et al.
 2012/0216359 A1 8/2012 Rogers et al.
 2012/0216360 A1 8/2012 Rogers et al.
 2012/0283693 A1 11/2012 Anderson et al.
 2012/0315201 A1 12/2012 Ferlic et al.
 2013/0030414 A1 1/2013 Gardner et al.
 2013/0072909 A1 3/2013 Solomon et al.
 2013/0136801 A1 5/2013 Tennican
 2013/0138083 A1 5/2013 Tennican
 2013/0138085 A1 5/2013 Tennican
 2013/0171030 A1 7/2013 Ferlic et al.
 2013/0199947 A1 8/2013 Tennican
 2013/0270270 A1 10/2013 Reinders
 2013/0335195 A1 12/2013 Rogers
 2013/0345645 A1 12/2013 Chelak
 2014/0135739 A1 5/2014 Solomon et al.
 2014/0150832 A1 6/2014 Rogers et al.
 2014/0182623 A1 7/2014 Vaillancourt et al.
 2014/0188089 A1 7/2014 Midgette et al.
 2014/0248181 A1 9/2014 Solomon et al.
 2014/0248182 A1 9/2014 Solomon et al.
 2014/0261558 A1 9/2014 Rogers et al.
 2014/0261581 A1 9/2014 Rogers
 2014/0366914 A1 12/2014 Kerr et al.
 2015/0018774 A1 1/2015 Anderson et al.
 2015/0086441 A1 3/2015 She et al.
 2015/0094694 A1 4/2015 Stone et al.
 2015/0217106 A1 8/2015 Banik et al.
 2015/0273199 A1 10/2015 Adams et al.
 2015/0314119 A1 11/2015 Anderson et al.
 2015/0314120 A1 11/2015 Gardner
 2016/0015959 A1 1/2016 Solomon et al.
 2016/0074648 A1 3/2016 Kerr et al.
 2016/0325089 A1 11/2016 Burkholz

FOREIGN PATENT DOCUMENTS

JP S-58-501359 A 8/1983
 JP 2001-258713 A 9/2001
 JP 2009-511181 A 3/2009
 JP 2010-516342 A 5/2010
 JP 5867703 B2 2/2016
 WO 87/00441 1/1987
 WO 99/29173 6/1999
 WO 2006/019782 A2 2/2006
 WO 2007/044760 A2 4/2007
 WO 2007/137056 A2 11/2007
 WO 2008/100950 A2 8/2008
 WO 2008/157092 A1 12/2008
 WO 2010/039171 A1 4/2010
 WO 2010/143693 A1 12/2010
 WO WO-2010141508 A1 12/2010
 WO 2011/053924 A1 5/2011
 WO 2011/066586 A1 6/2011
 WO 2015044904 A1 4/2015

OTHER PUBLICATIONS

“Patent Owner’s Preliminary Response Under 37 C.F.R. § 42,10,”
 USPTO, Patent Trial and Appeal Board, *Excelsior Medical Corpo-
 ration v. Becton, Dickinson and Company*, Case IPR2014-00880,
 U.S. Pat. No. 8,740,864, pp. 1-30, Sep. 16, 2014.
 “Decision, Institution of Inter Partes Review, 37 C.F.R. § 42,108,”
 USPTO, Patent Trial and Appeal Board, *Excelsior Medical Corpo-
 ration v. Becton, Dickinson and Company*, Case IPR2014-00880,
 U.S. Pat. No. 8,740,864, pp. 1-21, Nov. 25, 2014.
 3M Health Care, “3M Curox Jet Disinfecting Cap Video,” YouTube,
 Nov. 21, 2016, 1:12, 1:21-1:34. www.youtube.com/watch?v=MUNz7lmuK4.

* cited by examiner

FIG. 1

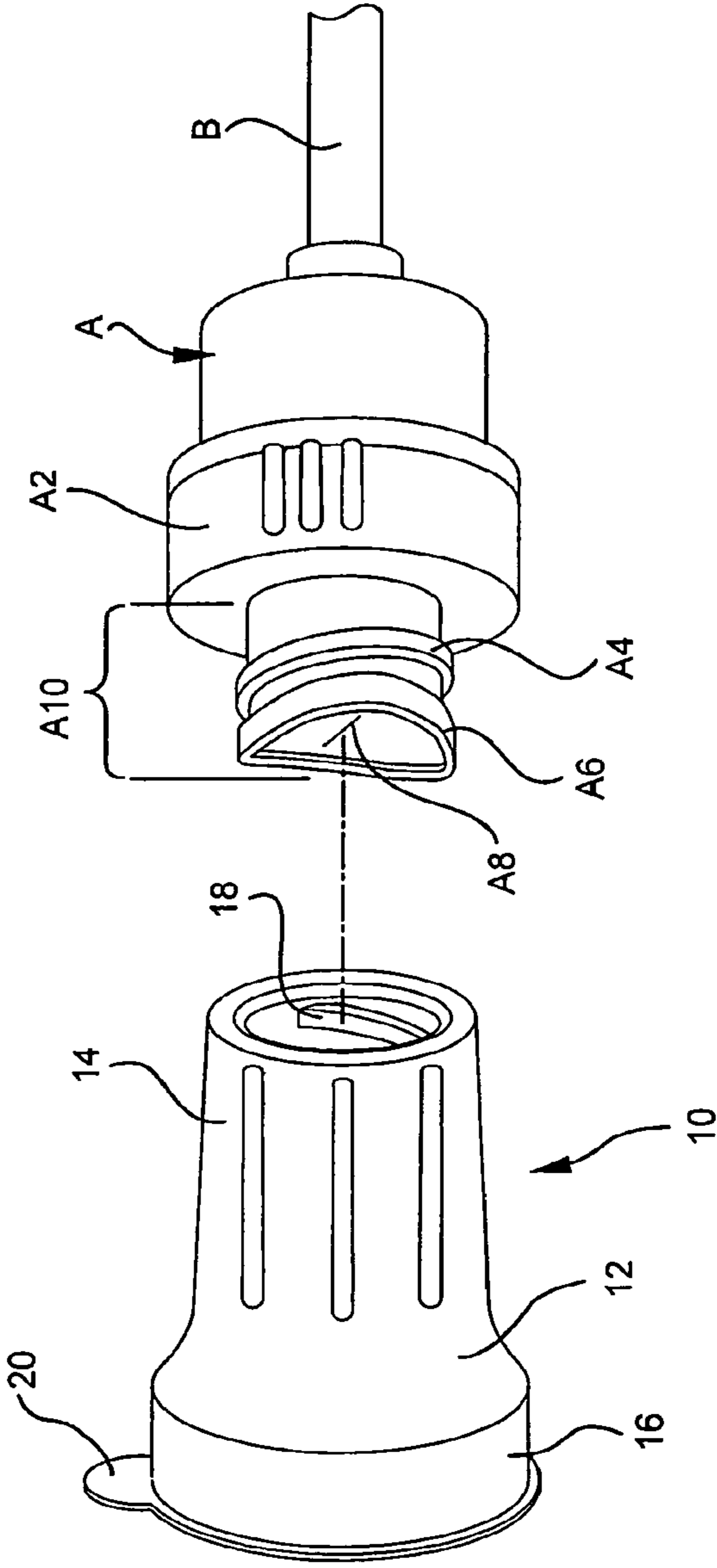


FIG. 2

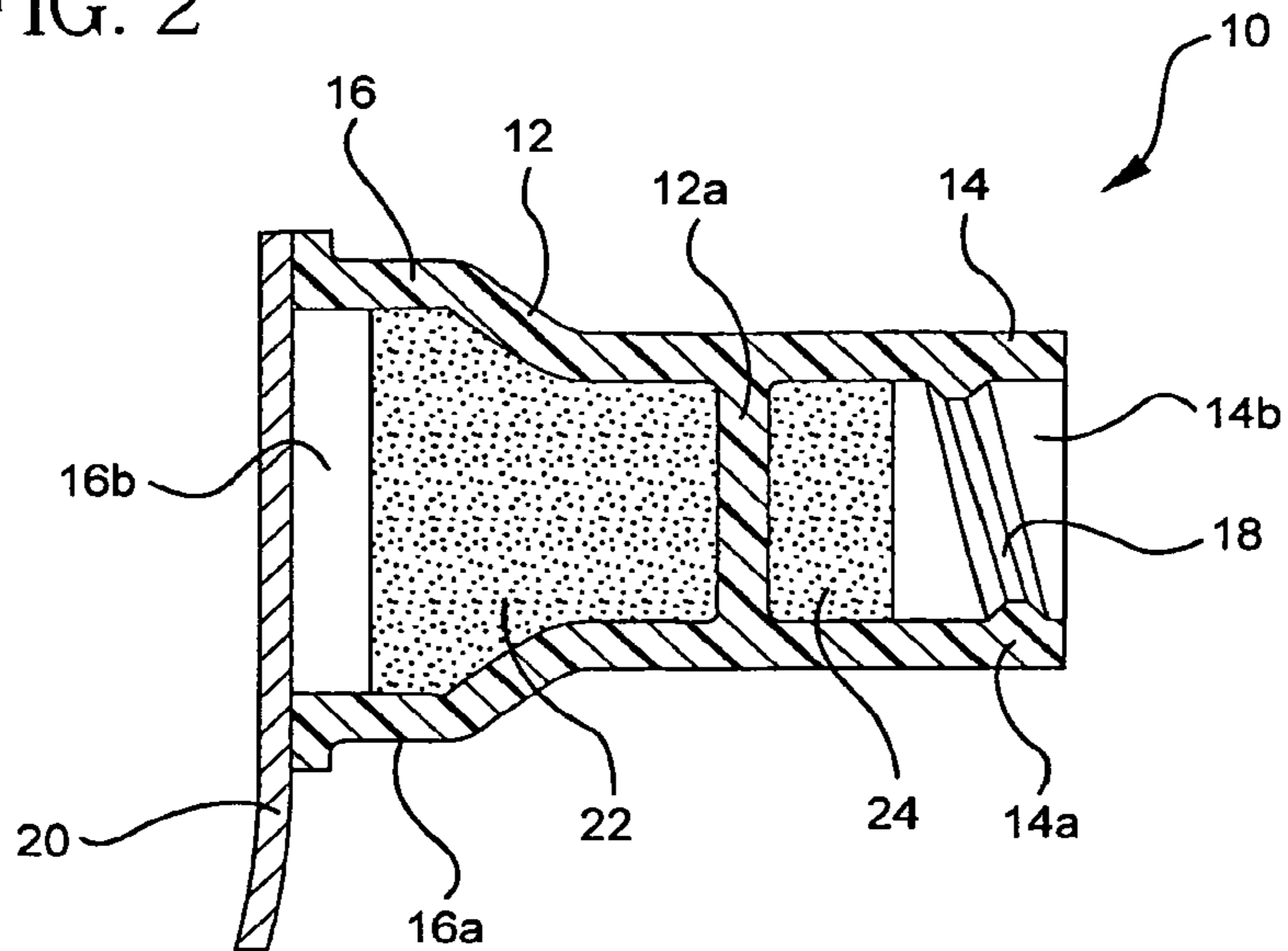


FIG. 3

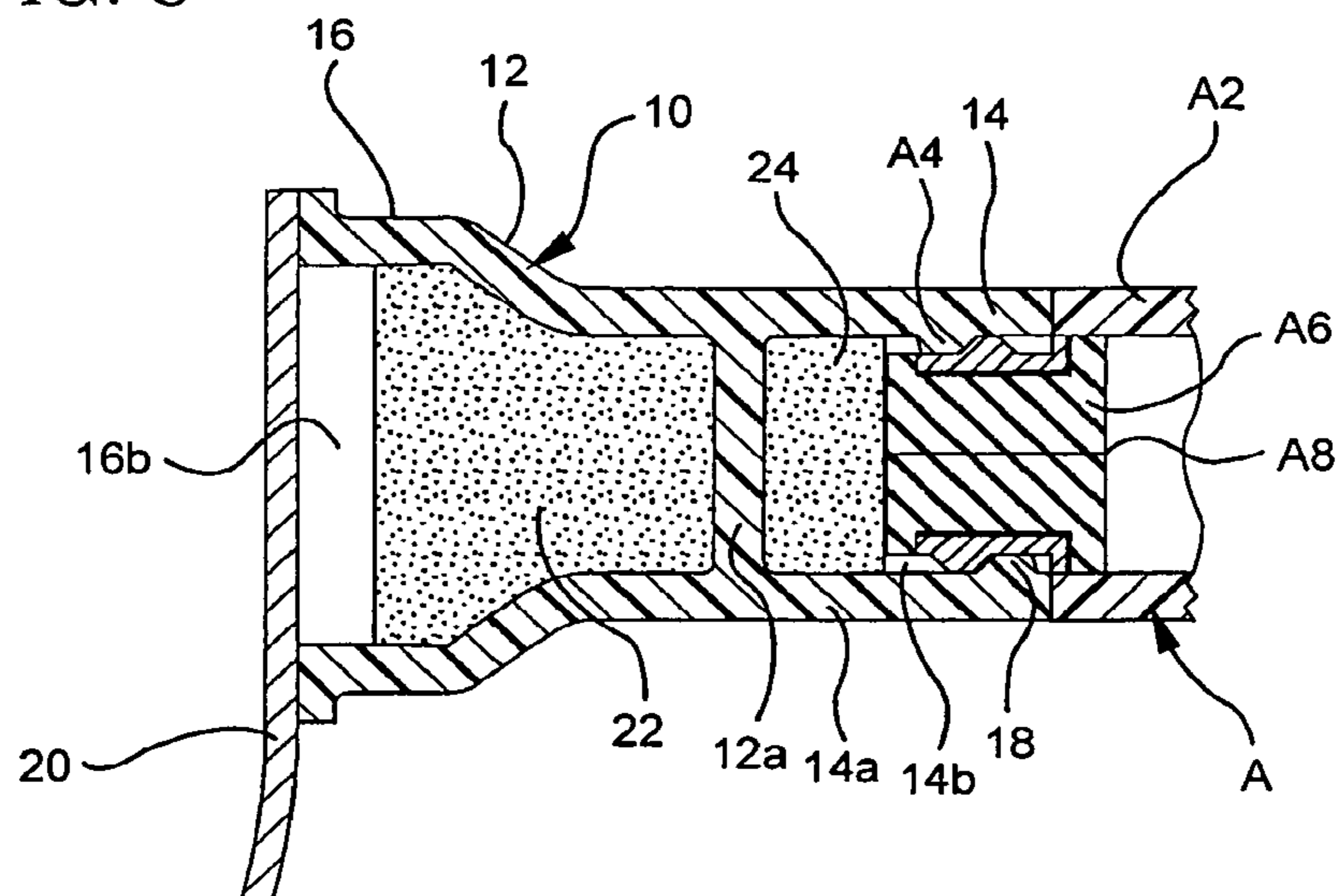


FIG. 4

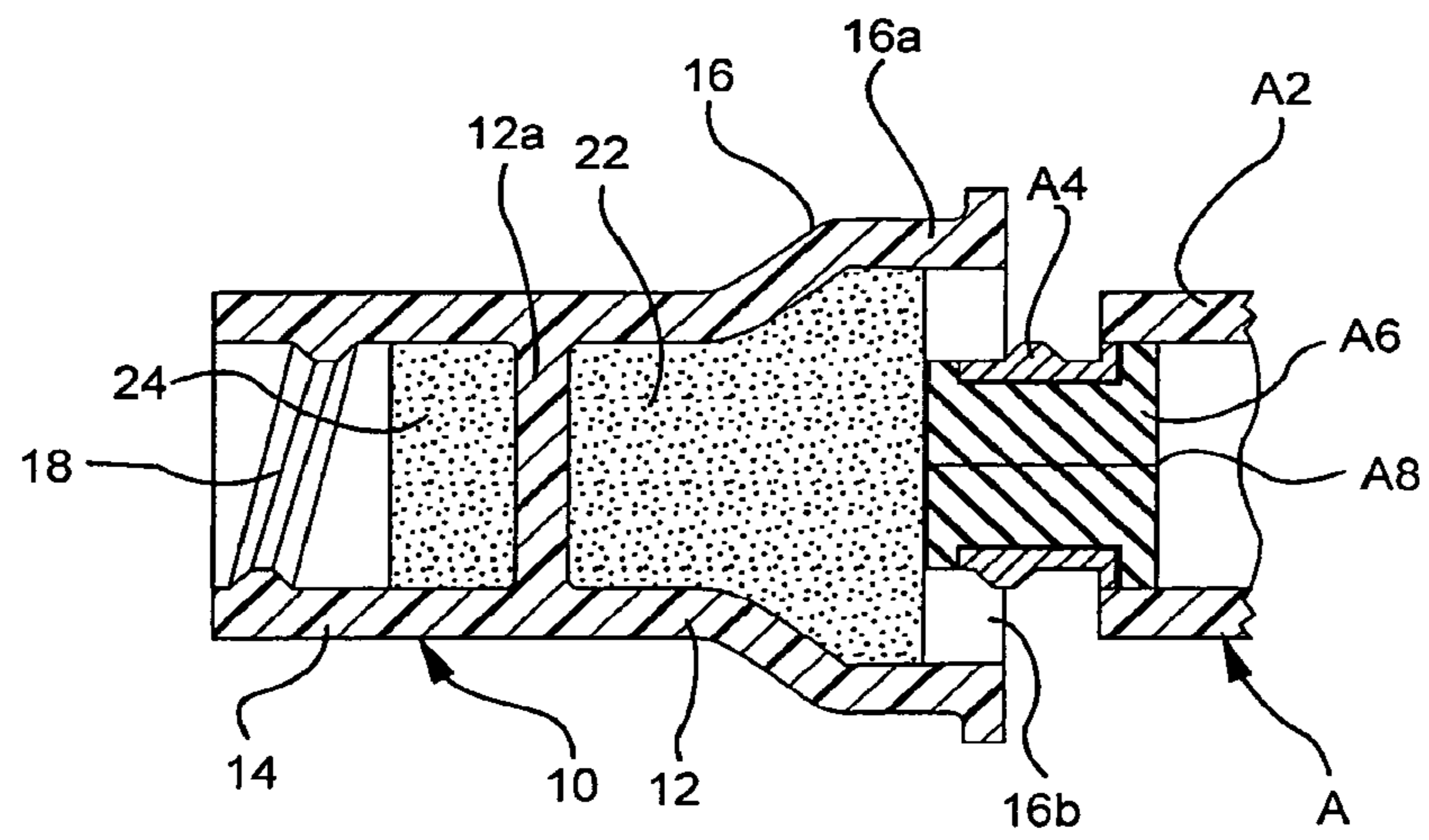


FIG. 5

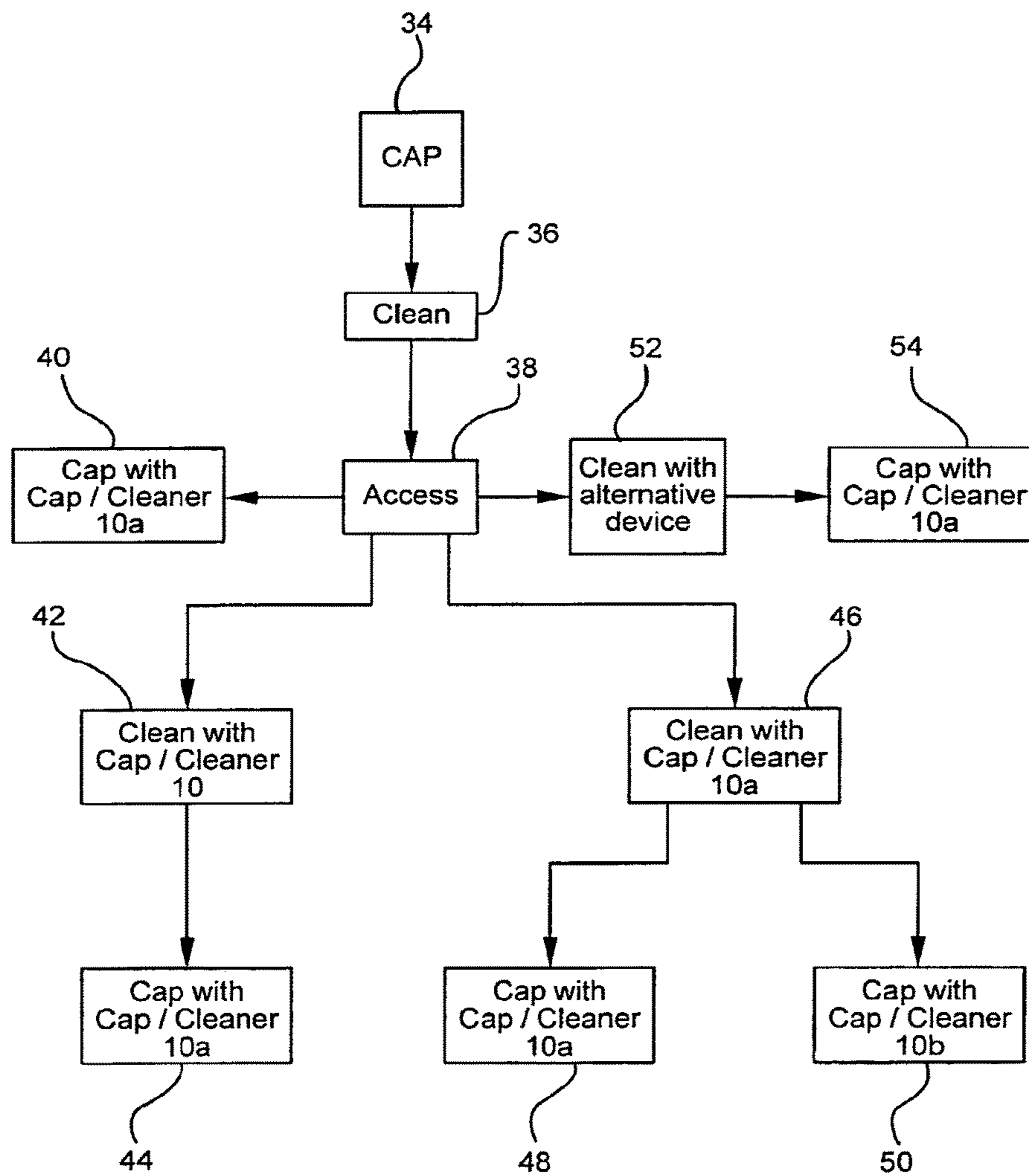


FIG. 6

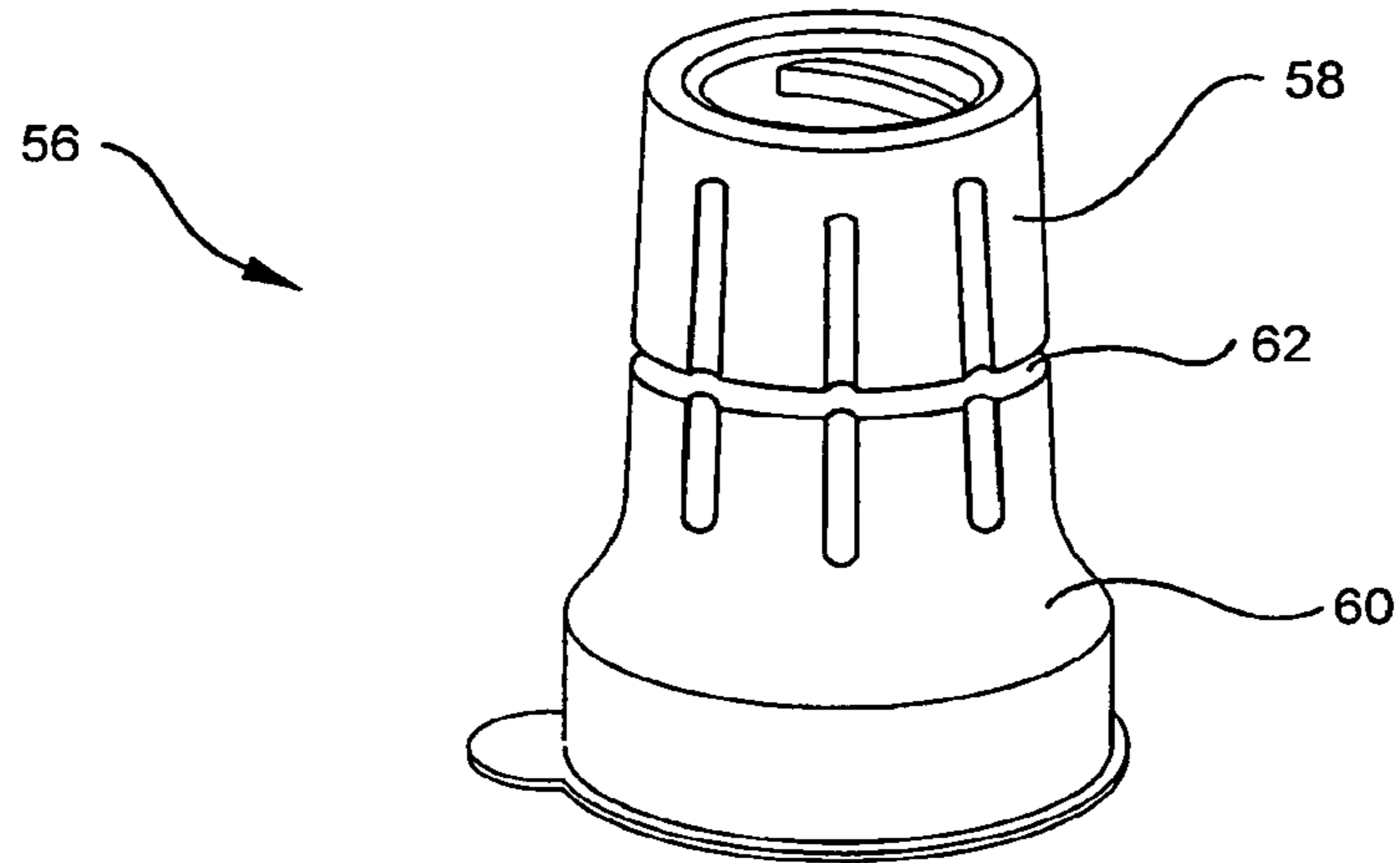


FIG. 7

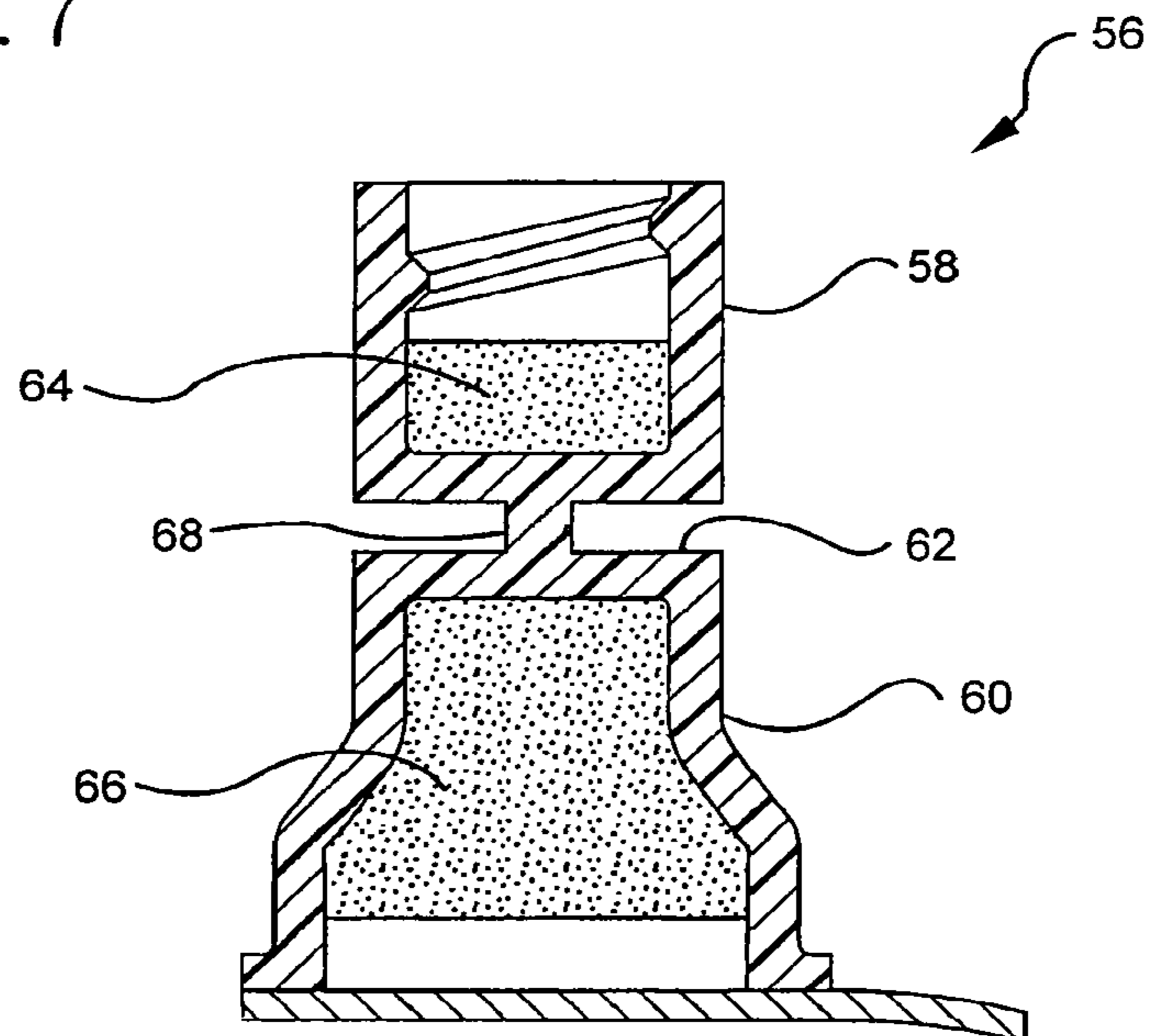


FIG. 8

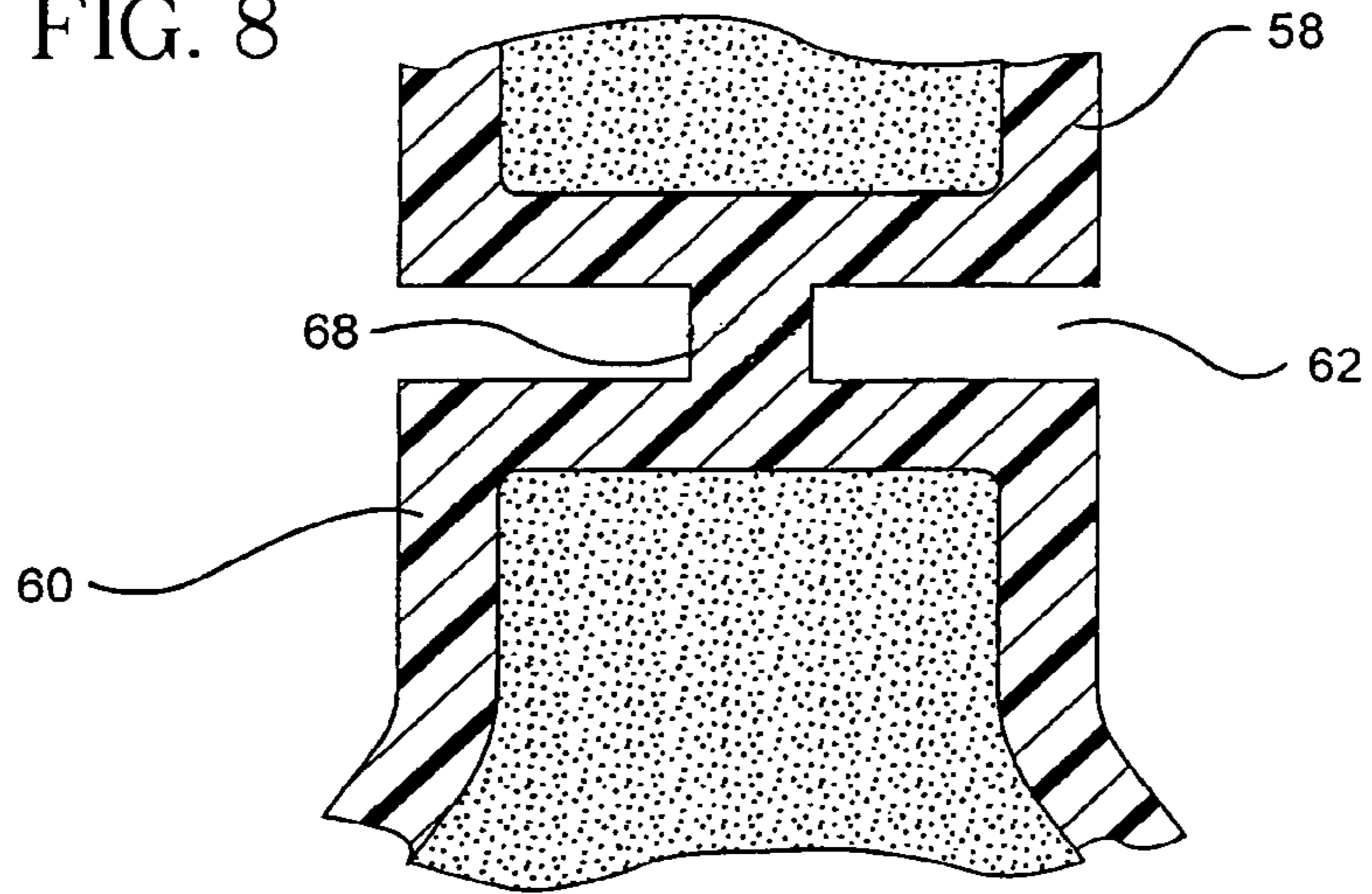


FIG. 9

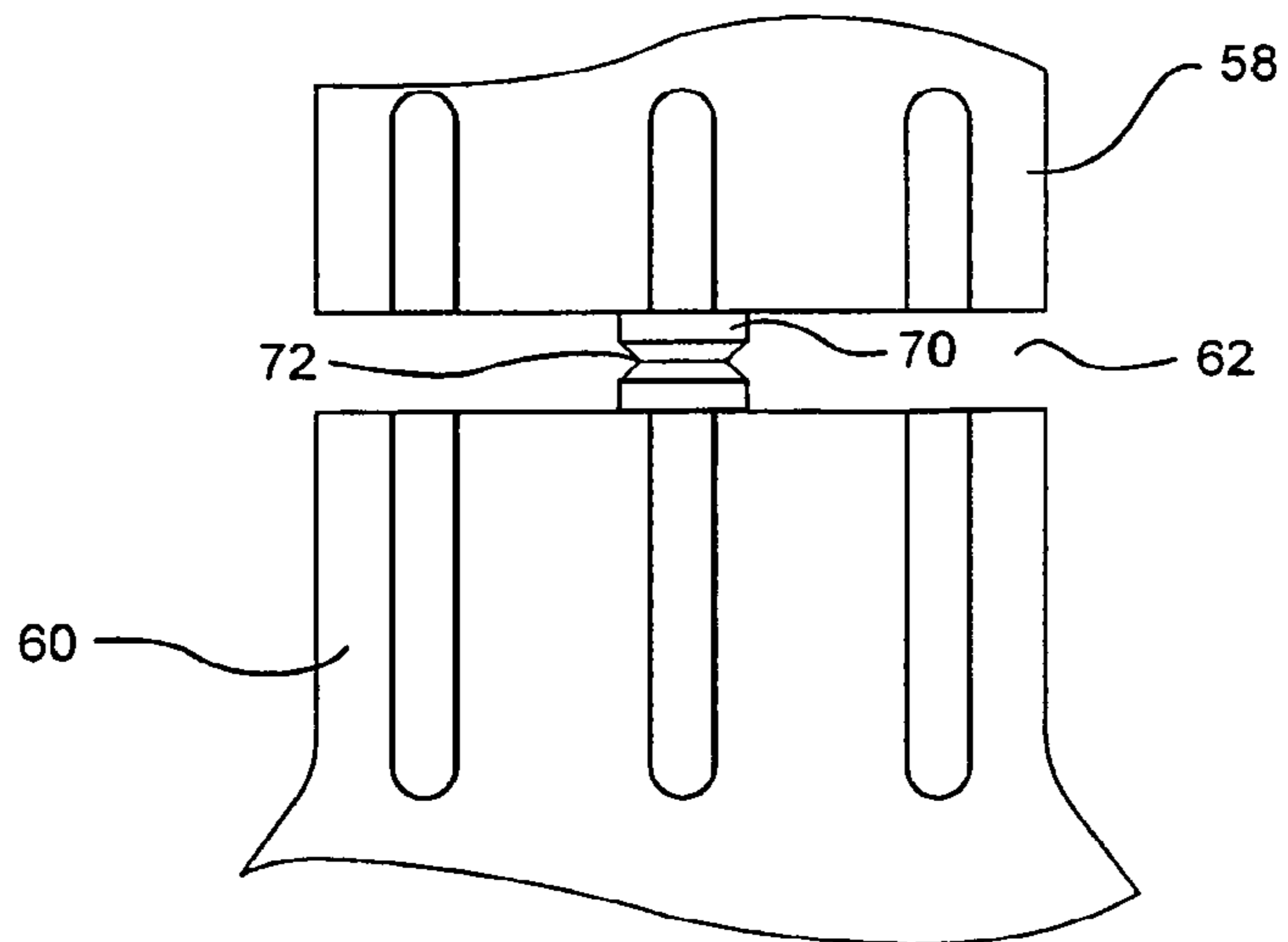


FIG. 10A

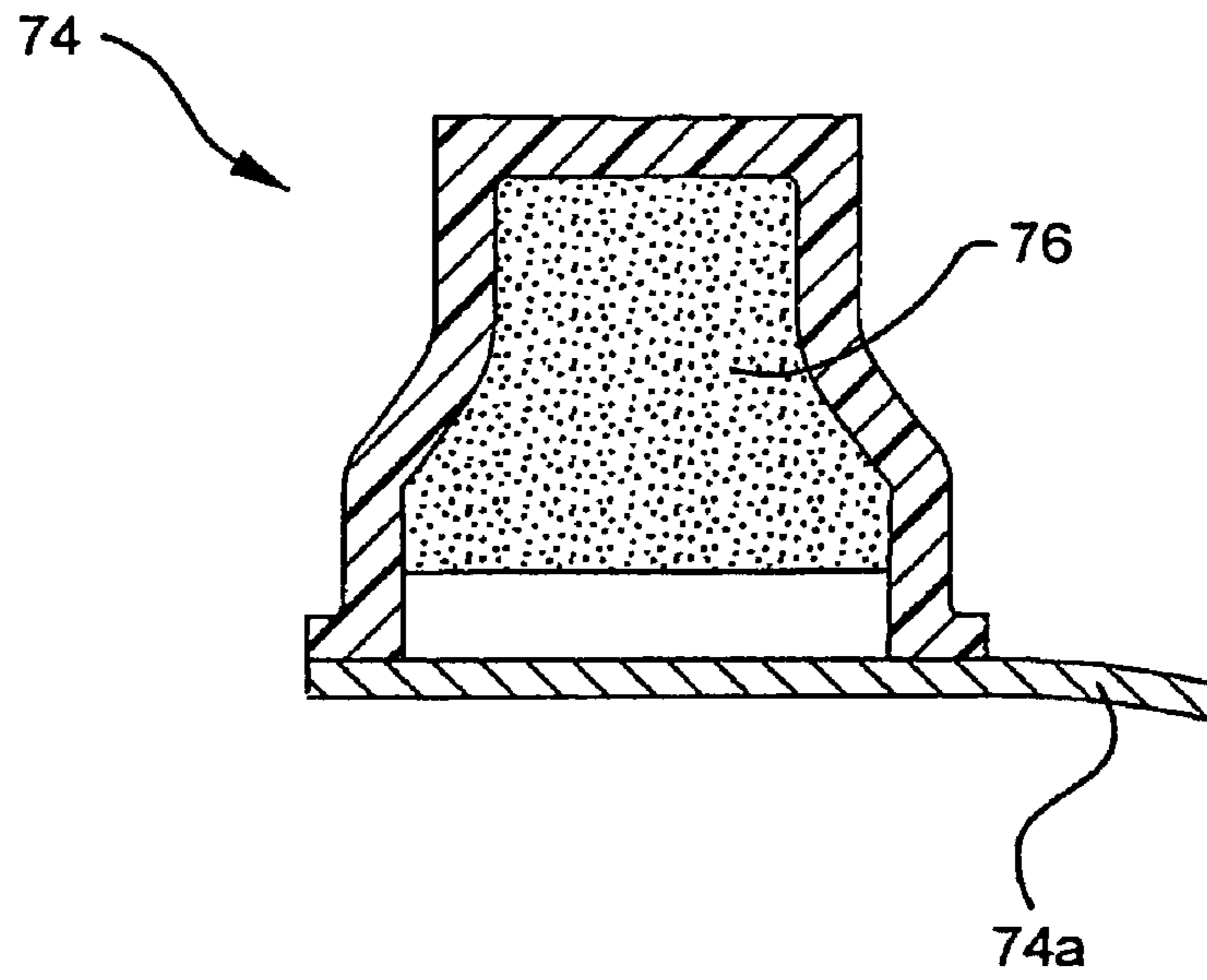
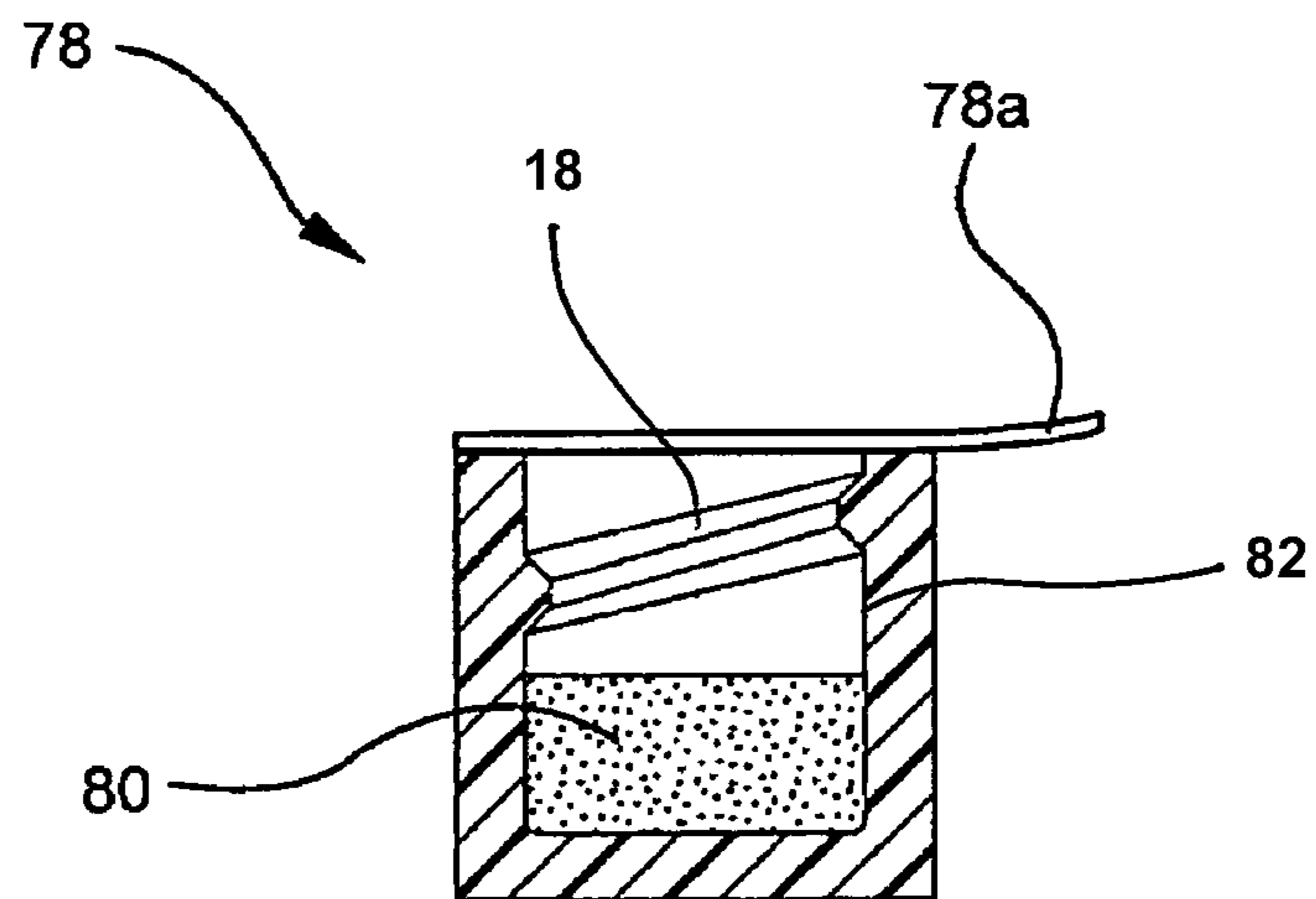


FIG. 10B



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PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 15/041,939, filed Feb. 11, 2016, which is a continuation of U.S. application Ser. No. 14/159,959, filed Jan. 21, 2014, titled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER, granted on Mar. 15, 2016 as U.S. Pat. No. 9,283,367, which is a continuation of U.S. application Ser. No. 11/281,711, filed Nov. 17, 2005, titled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER, granted on Jun. 3, 2014 as U.S. Pat. No. 8,740,864 which are incorporated herein in their entirety.

BACKGROUND OF THE INVENTION

Catheter-related bloodstream infections are caused by bacteria/fungi in patients with intravascular catheters. These infections are an important cause of illness and excess medical costs, as approximately 80,000 catheter-related bloodstream infections occur in U.S. intensive care units each year. In addition to the monetary costs, these infections are associated with anywhere from 2,400 to 20,000 deaths per year.

Guidelines from the Centers for Disease Control and Prevention describe various ways to limit catheter-related bloodstream infections in hospital, outpatient and home care settings. The guidelines address issues such as hand hygiene, catheter site care and admixture preparation. Despite these guidelines, 15 catheter-related bloodstream infections continue to plague our healthcare system.

Impregnating catheters with various antimicrobial agents is one approach that has been implemented to prevent these infections. These catheters, however, have given less than satisfactory results. In addition, some microbes have developed resistance to the various antimicrobial agents in the system.

In another system that is commercially available in Europe, a catheter hub containing an antiseptic chamber is filled with three percent iodinated alcohol. Though it has shown to be effective, the catheter hub is expensive and does not fare as well in a formal cost-benefit analysis. Therefore, there is a need for an effective and inexpensive way to reduce the number of catheter-related infections.

BRIEF SUMMARY OF THE INVENTION

The present invention is a device for antiseptically maintaining a patient fluid line access valve. The device includes a housing for covering the access portion of the access valve. A pad within the housing contacts the surface of the access portion of the access valve prior to (and optionally after) accessing the patient fluid line via the access valve to reduce the amount of microbes on the valve's access portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of a first representative embodiment of a cap/cleaner device and a patient fluid line access valve.

FIG. 2 is a cross-sectional side view of the first representative embodiment of the cap/cleaner device.

FIG. 3 is a cross-sectional side view of the first cap/cleaner device capping a patient fluid line access valve.

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FIG. 4 is a cross-sectional side view of the first cap/cleaner device cleaning a patient fluid line access valve.

FIG. 5 is a flow chart illustrating representative embodiments of methods of using the cap/cleaner device.

FIG. 6 is a perspective view of a second representative embodiment of a cap/cleaner device.

FIG. 7 is a cross-sectional side view of the second cap/cleaner device.

FIG. 8 is a cross-sectional view of a first separable connector.

FIG. 9 is a side view of a second separable connector.

FIG. 10A is a cross-sectional view of cleaning device.

FIG. 10B is a cross-sectional view of a capping device.

DETAILED DESCRIPTION

FIG. 1 shows an exploded view of patient fluid line access valve cap/cleaner device 10 with patient fluid line access valve A and patient fluid line B. Cap/cleaner 10 includes housing 12 with cap end 14, cleaning end 16 and thread 18; and lid 20. Access valve A includes housing A2 with thread A4 and septum A6 with slit A8. The exposed surface of septum A6 A10 ng with at least a portion of the exposed surface of housing A2 that surrounds septum A6, form access portion A10 of access valve A. Line B may be any of a number of types that include, for example, intravascular (IV) lines and catheters, saline wells, arterial lines and hemodialysis lines.

As will be described in more detail below, cap end 14 of cap/cleaner 10 attaches to access portion A10 of access valve A. Housing 12 is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, glycol-modified polyethylene terephthalate, acrylonitrile butadiene styrene or any other moldable plastic material used in medical devices.

Cap end 14 of housing 12 is open and contains thread 18 A10 ng the inside of the opening. Cleaning end 16 is covered by lid 20. Lid 20 is typically made of foil or similar type material and completely seals the opening (not shown) of cleaning end 16. Any type of material or seal may be used as long as a moisture barrier is provided.

FIG. 2 shows cap/cleaner 10 in more detail. In addition to the structures shown in FIG. 1, cap/cleaner 10 also includes internal wall 12a, hood 16a and chamber 16b of cleaning end 16, cap 14a and cavity 14b of cap end 14, wet pad 22 within chamber 16b and dry pad 24 within cavity 14b. Internal wall 112a separates cap end 14 and cleaning end 16.

Cap/cleaner 10 is typically distributed and stored in a sterile, sealed package either A10 one or paired with a patient fluid line access valve. One such type of valve is the BD Q-Syte™ valve from Becton, Dickinson and Company (illustrated in FIG. 1). However, cap/cleaner 10 is useful with any type of needleless or needle required access valve. Once removed from the package, cap/cleaner 10 is ready for use.

FIG. 3 illustrates cap/cleaner 10 covering access portion A10 of access valve A. Septum A6 provides an accessible seal for either a needle or a male luer taper. In the case of a needleless access device, such as that shown in FIG. 3, slit A8 extends through septum A6 to provide a port for insertion of the male luer taper.

As shown, cap end 14 includes cap 14a with cavity 14b, which contains dry pad 24. Dry pad 24 is impregnated with an antimicrobial agent to aid in maintaining antiseptic conditions of access portion A10 of valve A. Suitable material for dry pad 24 includes non-woven material or a foam sponge pad made of polyurethane, polyester, cotton or

any bioengineered plastic material such as silicone. Any of a number of antimicrobial agents may be used to impregnate dry pad **24**. Some examples include chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Alternatively, cap end **14** does not contain dry pad **24** and aids in maintaining antiseptic conditions by simply covering access portion **A10**.

In use, cap end **14** of cap/cleaner **10** is placed over access portion **A10** such that access portion **A10** is within cavity **14b** of cap end **14**. Cap/cleaner **10** may be attached either prior to or after placement of valve **A** for the patient. As shown in FIG. **3**, valve **A** includes thread **A4**. By rotating cap/cleaner **10** or valve **A** relative to one another, threads **A4** and **18** (of cap/cleaner **10**) interlock to provide a secured attachment. It is not necessary, however, for valve **A** to include thread **A4**. Cap end **14** will also attach and hold a luer slip, which does not have a thread. In other embodiments, cap/cleaner **10** may be manufactured without a thread.

The amount of material used for dry pad **24** can vary. Typically, there is enough material for dry pad **24** to contact at least septum **A6** of valve **A**. Enough space should be left in cavity **14b** of cap end **14** for access portion **A10** of valve **A** to be encompassed by cap end **14**, thus, maintaining antiseptic conditions of the surface. By maintaining antiseptic conditions of the surface, the risk of microbes penetrating into valve **A** is minimized.

To further minimize the opportunity for penetration by microbes, access portion **A10** is cleaned prior to accessing valve **A** with a needle or male luer taper. FIG. **4** illustrates cap/cleaner **10** cleaning access portion **A10** of valve **A**.

As shown in FIG. **4**, cleaning end **16** includes hood **16a** and chamber **16b**, which contains wet pad **22**. Wet pad **22** is impregnated with a cleaning agent and optionally, an antimicrobial agent. Wet pad **22** may be made from materials similar to those described for dry pad **24**.

The cleaning solution is typically an alcohol- or water-based solution. A suitable alcohol-based solution contains about 50% to about 100% (no additional water) of an alcohol solution. The balance of solutions that are less than 100% alcohol contain water and other optional materials such as fragrance, dye, surfactant, emollient, etc.

Suitable water-based solutions contain about 1% to about 10% alcohol solvent as a wetting agent and about 90% to about 99% water. Again, optional materials may also be added such fragrance, dye, surfactant, emollient, etc.

In an alternative embodiment, the cleaning solution also includes an antimicrobial agent. Any of a number of antimicrobial agents may be used in wet pad **22**. Some examples include chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Wet pad **22** and dry pad **24** may be impregnated with the same or different antimicrobial agents.

As shown in the Figures, cleaning end **16** is larger than cap end **14**. The hood of cleaning end **16** loosely encompasses at least access portion **A10** of valve **A**, and chamber **16b** is sized to allow some movement when access portion **A10** is inserted. The amount of material used for wet pad **22** will vary, but the amount should hold enough cleaning solution and allow enough movement for thorough cleaning. Wet pad **22** should be contained entirely within hood **16a** such that it is recessed inside chamber **16b** of cleaning end **16**.

In preparation for accessing valve **A**, cap end **14** is removed from valve **A** either by rotating cap/cleaner **10** to

release threads **18** and **A4** or by simply pulling if valve **A** does not have a thread. Lid **20** is removed from cleaning end **16**. Cleaning end **16** is then placed over at least access portion **A10**, such that wet pad **22** contacts septum **A6**. Though FIG. **4** only shows contact with septum **A6**, additional pressure may be applied such that wet pad **22** extends beyond the edges of septum **A6** to contact portions of the exposed surface of housing **A2**.

Next, for thorough cleaning, wet pad **22** should scrub access portion **A10** of valve **A**. Scrubbing may be accomplished by, for example, rotational movement or back and forth movement. Scrubbing should be carried out for a time long enough to allow the cleaning solution to at least disinfect access portion **A10** of valve **A**.

Once cleaned, valve **A** is ready to use. A needle or male luer taper is inserted to either infuse or withdraw fluid from the patient fluid line.

FIG. **5** is a flowchart illustrating representative embodiments of methods for using cap/cleaner **10**. Capping step **34**, cleaning step **36** and accessing step **38** were described above and are the same in each embodiment. However, upon withdrawal after accessing the patient fluid line, access portion **A10** of valve **A** may either be immediately capped or cleaned again prior to capping. If immediately capped, a new, second cap/cleaner **10A** is obtained and removed from its package. This is represented by step **40**. Cap end **14** of cap/cleaner **10A** is placed over access portion **A10** as described above. Cleaning end **16** of cap/cleaner **10A** is sealed and ready for the next time valve **A** is utilized.

Alternatively, access portion **A10** may be cleaned again prior to capping. This can be performed in one of the following ways. First, in step **42**, cleaning end **16** of cap/cleaner **10** is reused to clean access portion **A10**, which is then capped, at step **44**, with cap end **14** of a new, second cap/cleaner **10A**. Second, in step **46**, cleaning end **16** of a new, second cap/cleaner **10A** is used to clean access portion **A10**. Then, valve **A** maybe capped either with cap end **14** of cap/cleaner **10A** (step **48**) or of a new, third cap/cleaner **10B** (step **50**). Third, in step **52**, access portion **A10** may be cleaned with an alternative disposable cleaning device that is well known in the art. Examples of such cleaning devices include alcohol wipes, iodine swabs, etc. Once cleaned, cap end **14** of a new, second cap/cleaner **10A** may be attached to valve **26** (step **50**).

Additional embodiments of the present invention include separable and individual, uncoupled devices. FIG. **6** shows separable cap/cleaner **56**. Separable cap/cleaner **56** includes cap end **58**, cleaning end **60** and gap **62**. Gap **62** is the separation between cap end **58** and cleaning end **60**.

FIG. **7** shows separable cap/cleaner **56** in more detail and further includes dry pad **64** within cap end **58**, wet pad **66** within cleaning end **60** and breakable connector **68**. In use, separable cap/cleaner **56** operates as described above for cap/cleaner **10** except that cleaning end **60** may be removed after cleaning access portion **A10** of valve **A**. Detaching cleaning end **60** reduces bulkiness from separable cap/cleaner **56** by only maintaining cap end **58** over access portion **A10**.

FIG. **8** shows a representative embodiment of breakable connector **68**. Connector **68** is typically made of the same material from which housing **12** is fabricated. Torsional shearing caused by twisting cap end **58** and/or cleaning end **60** relative to each other may be used to break connector. Alternatively, a three-point bending force, which consists of a fulcrum (connector **68**) that directs a force vector contralateral to the direction of the terminal (cap end **58** and

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cleaning end 60) force vectors, may be applied for breaking connector 68. Once removed, cleaning end 60 may be discarded.

FIG. 9 is an alternate embodiment showing notched breakable connector 70. Notch 72 within connector 70 is an area of reduced cross-sectional area, which acts as a score to facilitate breaking of connector 70.

Other separation mechanisms may also be used to remove cleaning end 60 from cap end 58. For instance, a luer lock type mechanism can be utilized to separate ends 58 and 60 from each other.

FIG. 10A shows a representative embodiment of cleaning device 74 with lid 74a and wet pad 76. Here, cleaning device 74 is a stand-alone device that is used as described above for cleaning end 16.

FIG. 10B shows a representative embodiment of cap device 78 with lid 78a and pad 80. Cap device 78 is a stand-alone device where pad 80 may either be a wet pad or a dry pad. Where pad 80 is a dry pad, cap device 78 is used as described above for cap end 14.

Where pad 80 is a wet pad, cap device 78 may be used to clean access portion A10 of valve A in addition to its capping function. The twisting motion involved in removing and placing cap device 78 with respect to access portion A10 provides friction for cleaning. Additional cleaning can be accomplished by twisting cap device 78 in one direction and then in the reverse direction for a desired amount of time.

Cap device 78 further comprises an inner circumference 82 that defines a cavity in which pad 80 is housed. In some instances, cap device 78 comprises a thread or threading 18 having a length that is less than inner circumference 82.

With either cleaning device 74 or cap device 78, additional gripping surface may be added by extending the length of the housing. The increased gripping surface would provide easier handling of devices 74 and 78.

Cap/cleaner 10 cleans and maintains access valves in antiseptic or aseptic condition. This substantially decreases the risk of patient infections caused by the ingress of microbes into the access valves, particularly for needleless access valves.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

The invention claimed is:

1. A device for cleaning a patient fluid line access valve comprising:

a cap having an inner sidewall and an opening to an inner cavity, the opening for receiving an access portion of an access valve, the access portion providing an access to a fluid line via the access valve when connected to the fluid line;

a thread at least partially disposed on at least a portion of the inner sidewall of the cap;

a pad including a cleaning agent, the pad at least partially disposed in the inner cavity and adapted to clean at least a portion of the access portion of the access valve;

a space providing an air passage between an inner circumference of the cap and at least a portion of an outer surface of a sidewall of the access portion of the access valve when the access portion is received in the opening of the cap and when the inner sidewall of the cap

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comprising the thread provides a secured attachment of the cap to the access valve;

and

a removable seal attached to the cap to cover the opening to the inner cavity, the pad being disposed in the inner cavity, prior to receipt of the access portion of the access valve.

2. The device of claim 1, wherein the access portion comprises a luer slip and the cap attaches thereto.

3. The device of claim 2, wherein the space comprises a gap between the thread and an external surface of the luer slip.

4. The device of claim 2, wherein the space comprises a helical void formed between the thread and an external surface of the luer slip, received via the opening, in the inner cavity.

5. The device of claim 1, wherein the access portion of the access valve comprises a thread, and the secured attachment comprises the thread of the cap accommodating at least a portion of the thread of the access portion.

6. The device of claim 5, wherein the space comprises a gap between the thread of the cap and the thread of the access portion.

7. A device for cleaning a patient fluid line access valve comprising:

a cap having an opening to an inner cavity, the opening for receiving an access portion of an access valve, the access portion providing an access to a fluid line via the access valve when connected to the fluid line;

a pad including a cleaning agent, the pad at least partially disposed in the inner cavity and adapted to clean at least a portion of the access portion of the access valve;

a space between an inner circumference of the cap and at least a portion of an outer surface of a sidewall of the access portion of the access valve received in the opening of the cap;

a removable seal attached to the cap to cover the opening to the inner cavity, the pad being disposed in the inner cavity, prior to receipt of the access portion of the access valve; and

a thread at least partially disposed on the inner circumference of the cap,

wherein

the access portion of the access valve comprises a thread, and

the space comprises a helical void formed by a dimensional difference between the thread of the cap and the thread of the access portion when the thread of the cap accommodates the thread of the access portion.

8. The device of claim 5, wherein the cap is attached to the access portion.

9. The device of claim 1, wherein the cap encompasses at least a portion of the access portion to allow movement of the access portion, received via the opening, in the inner cavity.

10. A device for cleaning a needleless access valve comprising:

a cap having an inner cavity for receiving an access portion of an access valve, and an opening to the inner cavity for receiving the access portion of the access valve into the inner cavity, the access portion providing an access to a fluid line via the access valve when connected to the fluid line;

a thread at least partially extending inwardly into the inner cavity of the cap to provide a secured attachment of the cap to at least a portion of the access portion of the access valve received into the inner cavity to maintain the cap on the access valve;

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a cleaning agent disposed in the inner cavity, the cleaning agent being formulated to clean at least a portion of the access portion of the access valve received in the inner cavity of the cap;

and

a removable seal sealing the cleaning agent within the inner cavity prior to the inner cavity of the cap receiving the access portion of the access valve,

wherein a space providing an air passage is formed between an inner circumference of the cap and at least a portion of an outer surface of a sidewall of the access portion of the access valve when the access portion is received in the opening of the cap and when the secured attachment comprises holding at least a portion of the outer surface of the sidewall of the access portion of the access valve within the inner cavity of the cap.

11. The device of claim 10, wherein

the cap encompasses the access portion of the access valve received into the inner cavity of the cap to allow lateral movement of the access portion within the inner cavity when the access portion is received into the inner cavity.

12. The device of claim 10, wherein the thread has a length less than an inner circumference of the inner cavity.

13. The device of claim 10, wherein:

the thread is configured at least partially around an inside surface of the cap near an outer periphery of the inner cavity to accommodate corresponding threads on the access portion of the access valve;

and

the space comprises a gap between the portion of the outer surface of the sidewall of the access portion and the

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inside surface of the cap comprising the thread when the access portion is received in the inner cavity and when the secured attachment is provided.

14. A device for cleaning a needleless access valve having a threaded access portion comprising:

a cap having an inner cavity for receiving a threaded access portion of a valve via an opening to the inner cavity, the threaded access portion providing an access to a fluid line via the access valve when connected to the fluid line;

a protrusion extending inwardly at least partially around an inside surface of the cap, the protrusion to attach the cap to at least a portion of the threaded access portion of the valve received in the inner cavity to maintain the cap on the valve;

a cleaning agent disposed in the inner cavity, the cleaning agent being formulated to clean at least a portion of the threaded access portion of the valve received in the inner cavity; and

a removable seal covering the opening to the inner cavity, the cleaning agent being within the inner cavity of the cap,

wherein a space providing an air passage is defined at least between a portion of an outer surface of a sidewall of the threaded access portion and the inside surface of the cap comprising the protrusion when the threaded access portion is received in the inner cavity and the cap is attached to the valve.

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